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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/700,906	11/04/2003	Benjamin Oshlack	200.1133CON5	1129

7590 12/10/2009

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EXAMINER	
SHEIKH, HUMERA N	

ART UNIT	PAPER NUMBER
1615	

MAIL DATE	DELIVERY MODE
12/10/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/700,906	OSHLACK ET AL.	
	Examiner	Art Unit	
	Humera N. Sheikh	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 September 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *75-86,89,91 and 92* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *75 and 85* is/are rejected.

7)☒ Claim(s) *76-84,86,89,91 and 92* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *4/13/09;6/15/09;6/17/09;7/22/09;10/1/09;10/9/09*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Application

Receipt of the Response and Amendment after Non-Final Office Action filed 09/08/09 and the Information Disclosure Statements (IDS) filed 04/13/09, 06/15/09, 06/17/09, 07/22/09, 10/01/09 and 10/09/09 is acknowledged.

Applicant has overcome the following rejections by virtue of the amendment to the claims and/or persuasive remarks: (1) The 35 U.S.C. §112 second paragraph rejection for claim 82 has been withdrawn; (2) The 35 U.S.C. §103(a) rejection of claims 75-86 over Kreek et al. (U.S. Pat. No. 4,987,136); Kaiko *et al.* (U.S. Pat. No. 6,277,384) and Kuczynski *et al.* (WO 97/33566) have been withdrawn.

Claims 75-86, 89, 91 and 92 are pending in this action. Claims 75-77, 82, 89 and 91 have been amended. Claims 1-74, 87, 88 and 90 have previously been cancelled. Claims 75 and 85 remain rejected. Claims 76-84, 86, 89, 91 and 92 are objected to.

* * * * *

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 75 and 85 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Namely, claim 85 which

recites language drawn to the "prevention (or reversal) of the effects of opioids" renders the claims non-enabling. The factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have been described in In re Wands, 8 USPQ2d 1400 (Fed. Cir. 1988). Among these factors are: (1) the nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary. When the above factors are weighed, it is the examiner's position that one skilled in the art could not practice the invention without undue experimentation.

(1) The nature of the invention/(5) The breadth of the claims:

The nature of the invention is directed to a dosage form comprising particles consisting of an opioid antagonist, a means for sequestering the opioid antagonist and one or more pharmaceutical excipients, whereby the dosage form is an oral dosage form and whereby if the dosage form is subjected to tampering, such as by crushing, chewing, grinding, etc., will produce a physiological effect. The claims are quite broad and permit additional components (i.e., auxiliaries, excipients, additional active agents) in the dosage form. Furthermore, the claims do not recite specific ingredients, such as a specific hydrophobic material, which is used as the 'sequestering means'.

(2) The state of the prior art:

The prior art teachings provide for compositions comprising the use of opioid antagonists, opioid agonists and sustained release coating materials. The compositions can be in various forms, which include, tablets, capsules, lozenges, emulsions and the like (see for instance, Palermo WO 99/32120).

(3) The relative skill of those in the art:

The relative skill of those in the art is high, such as Ph.D. or M.D. level technology.

(6) The amount of direction or guidance presented:

The specification filed 11/04/03, discloses 'that the physiological effect is the prevention of euphorigenic effects'. It is unclear to the Examiner as to how the instant invention can "prevent" such euphorigenic effects using the composition claimed herein. The specification establishes that various unique and specific ingredients are combined to result in the instant dosage form in order to avoid the "euphorigenic effects". However, the claim limitation of the "prevention of euphorigenic effects" renders the claims non-enabling since the specification provides no guidance on how the prevention of these effects would be provided through the use of merely an antagonist, a means for sequestering and an optional pharmaceutical excipient, as is instantly claimed (see claim 75 for instance).

(7) The presence or absence of working examples:

The working examples are insufficient to establish the instant "prevention of euphorigenic effects". The examples are distinct from the scope of the claims and there are no formulations of the claims presented which would be representative of the examples shown in the instant specification.

(8) The quantity of experimentation necessary:

When the above factors are weighed together, it is the position of the Examiner that the instant invention would require 'undue' and painstaking experimentation to arrive at the instant invention to determine which particular combination of ingredients and in which particular amounts and/or ratios would be needed to "prevent" euphorigenic effects as is instantly claimed by Applicant.

It is suggested that the term "prevention" be deleted to overcome this rejection.

* * * * *

Allowable Subject Matter

Claims 76-84, 86, 89, 91 and 92 are objected to as being dependent upon a rejected base claim, but would be allowable once the rejection of the base claim (and intervening claims) has been overcome.

Response to Arguments

Applicant's arguments, see Response pages 8-11, filed 09/08/09, with respect to the rejection(s) of claim(s) 82 under 35 U.S.C. 112, 2nd paragraph (for lack of antecedent basis) and

the rejection of claims 75-86, 89 and 91 under 35 U.S.C. 103(a) over Kreek ('136); Kaiko ('384) and Kucznynski ('566) have been fully considered and are persuasive. Therefore, the rejections have been withdrawn. However, the 35 U.S.C. 112, 1st paragraph rejection with respect to the term "prevention" in claim 85 has been maintained herein, for the reasons of record discussed above. In addition, Applicant has not imparted any special definition with respect to the term "prevention" in their specification. It is suggested that the term "prevention" be deleted to overcome the 112, 1st paragraph rejection.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

--No claims are allowed at this time.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Humera N. Sheikh whose telephone number is (571) 272-0604. The examiner can normally be reached on Monday-Friday during regular business hours.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert A. Wax, can be reached on (571) 272-0623. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Humera N. Sheikh/

Primary Examiner, Art Unit 1615

hns

December 6, 2009